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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,123	04/05/2001	Yoshiharu Doi	07898-070001	9955
7590 01/30/2004				
Fish & Richardson 4350 La Jolla Village Drive Suite 500 San Diego, CA 92122			EXAMINER HUTSON, RICHARD G	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 01/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/807,123

### Applicant(s)

DOI ET AL.

### Examiner

Richard G Hutson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/8/2003 has been entered.

Applicants amendment of claims 1, 2, 4, 6, and the cancellation of claims 13-15, Paper of 12/8/2003, is acknowledged. Claims 1-13 are at issue and are present for examination. Applicants' arguments filed on 12/8/2003, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

### ***Claim Objections***

Claims 2, 4 and 6 are objected to because of the following informalities:

Claims 2, 4 and 6 are objected to in that the newly amended recitation (using claim 2 as an example) "(b) a protein having an amino acid sequence including deletion, substitution, or addition of **two or more amino acids** relative to the amino acid sequence represented by SEQ ID NO: 2 or 4, and having polyester polymerase activity,

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wherein the number of deleted, substituted, or added amino acids is between **2 and 10**" is somewhat confusing. While it is understood that the number of deleted, substituted, or added amino acids must be between **2 and 10**, the recitation of "two or more amino acids" is confusing in light of this and it is suggested that the claim be amended so that it reads as clearly encompassing a number of deleted, substituted, or added amino acids that is between **2 and 10**. Claims 4 and 6 are similarly objected to.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is stated in the previous office action as it applied to previous claims 1-15. In response to this rejection applicants have amended the claims and traverse the rejection as it applies to the newly amended claims.

Applicants state that they have amended claim 1 to remove the recitation of "a DNA selected from the group consisting of" and argue that this amendment in light of the examiner's previous comments that "Applicants have support for a disruption by a

recombinant vector which contains a polyester polymerase gene, a  $\beta$ -ketothiolase gene and a NADPH-acetoacetyl CoA reductase gene" should accordingly cause the withdrawal of the rejection.

Applicants argument is not found persuasive and it is noted to applicants that these previous comments by the examiner were taken out of context. These previous examiner's comments were made contrasting the support for "recombinant vector which contains a polyester polymerase gene, a  $\beta$ -ketothiolase gene and a NADPH-acetoacetyl CoA reductase gene" with a "recombinant vector which contains **any DNA selected from any** polyester polymerase gene, any  $\beta$ -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene".

Applicants claims 1, 8-12 continue to be directed to all possible transformants comprising a host, wherein a polyhydroxybutanoic acid polymerase gene in the host cell is disrupted with a recombinant vector containing any polyester polymerase gene, any  $\beta$ -ketothiolase gene and any NADPH-acetoacetyl CoA reductase gene (claim 1).

One would not recognize from the disclosure that applicant was in possession of the claimed invention. Specifically applicants were not in possession of all possible polyhydroxybutanoic acid polymerase genes nor all possible host cells comprising such a polyhydroxybutanoic acid polymerase gene, nor all possible polyester polymerase genes, all possible  $\beta$ -ketothiolase gene and all possible NADPH-acetoacetyl CoA reductase genes. The specification provides a single representative species of transformant, *Pseudomonas* sp. strain 61-3 (JCM10015) transformed with a recombinant vector comprising the DNA sequences of SEQ ID NOs : 1 or 3, 5, and 7,

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encompassed by these claims. Given this lack of additional representative species as encompassed by the claims, Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

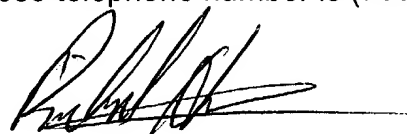
Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at [www.uspto.gov](http://www.uspto.gov).

Further applicants amendment of claims 2, 4 and 6 such that they recite "two or more amino acids" is not supported by the original specification and is thus considered new matter (See also above 112 second paragraph rejection).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

A handwritten signature in black ink, appearing to read 'Richard G. Hutson', with a long horizontal line extending to the right.

Richard G Hutson, Ph.D.

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Primary Examiner

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1/24/2004